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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/626,096	07/26/2000	Robert M Umek	A-68271-2/RFT/RMS/RMK	8157

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EXAMINER	
CALAMITA, HEATHER	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 06/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/626,096	UMEK ET AL.	
	Examiner	Art Unit	
	Heather G. Calamita, Ph.D.	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *May 16, 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *60-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *60-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S-0.0.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 16, 2005, has been entered.

Status of Application, Amendments, and/or Claims

2. Claims 60-69 are currently under examination. Any objections and rejections not reiterated below are hereby withdrawn.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 60, 66 and 67 are rejected under 35 U.S.C. 102(b) as being anticipated by Meade et al. (USPN 6,177,250 01/23/2001).

Meade et al. teach (claim 60), a method of determining the identification of nucleotide(s) at a first detection position in a first domain of a target sequence, said target sequence comprising said first domain and a second domain, said method comprising:

a. providing an electrode with a covalently attached capture probe, wherein said capture probe has a sequence substantially complementary to said second domain of said target sequence (see col. 9 lines 63-67 see col. 21 lines 59-60);

b. contacting said electrode with:

(i) said target sequence;

(ii) a first label probe substantially complementary to said first domain, comprising a first nucleotide at an interrogation position and a first electron transfer moiety (ETM) with a first redox potential (see col. 7 lines 25-27, col. 21 lines 59-67, col. 22 lines 1-13);

(iii) a second label probe substantially complementary to said first target domain, comprising a second nucleotide at said interrogation position and a second ETM with a second redox potential; under conditions wherein if said nucleotide at said interrogation position is perfectly complementary to said detection position, hybridization of said probe(s) occurs; and detecting the presence of said first and/or second ETM to determine the nucleotide(s) at said detection position (see col. 7 lines 25-27, col. 21 lines 59-67, col. 22 lines 1-13).

With regard to claims 66-67, Meade et al. teach transition metal complexes (see abstract).

4. Claims 60, 64 and 66-69 are rejected under 35 U.S.C. 102(e) as being anticipated by Blackburn et al. (USPN 6,686,150 B1, 02/03/2004).

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that

any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Blackburn et al. teach (claim 60), a method of determining the identification of nucleotide(s) at a first detection position in a first domain of a target sequence, said target sequence comprising said first domain and a second domain, said method comprising:

a. providing an electrode with a covalently attached capture probe, wherein said capture probe has a sequence substantially complementary to said second domain of said target sequence (see col. 7 lines 20-24, Fig 16C);

b. contacting said electrode with:

(i) said target sequence;

(ii) a first label probe substantially complementary to said first domain, comprising a first nucleotide at an interrogation position and a first electron transfer moiety (ETM) with a first redox potential (see col. 7 lines 44-46, Fig 16 H);

(iii) a second label probe substantially complementary to said first target domain, comprising a second nucleotide at said interrogation position and a second ETM with a second redox potential; under conditions wherein if said nucleotide at said interrogation position is perfectly complementary to said detection position, hybridization of said probe(s) occurs; and detecting the presence of said first and/or second ETM to determine the nucleotide(s) at said detection position (see col. 7 lines 44-46, Fig 16 H).

With regard to claim 64, Blackburn et al. teach the first label probe contains a plurality of first ETMS (see col. 45 line 64).

With regard to claims 66-69, Blackburn et al. teach the transition metal complex of ferrocene, a metalocene (see Figures 2-5 and col. 45 lines 41-44).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 61-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meade et al. (USPN 6,177,250 01/23/2001) in view of Heller et al. (USPN 5,605,662, 02/25/1997).

The teachings of Meade et al. are described previously.

Meade et al. do not teach an array (more than two label probes each with an ETM having a redox potential).

Heller et al. teach an array (see col. 6 lines 52-56).

It would have been prima facie obvious to utilize the method of detection of nucleic acids with ETMs as taught by Meade et al. (USPN 6,177,250 01/23/2001) in an array format as taught by Heller et al. (USPN 5,605,662, 02/25/1997). An ordinary practitioner would have been motivated to utilize the method of detection of nucleic acids with ETMs in an array format as taught by Heller et al. (USPN 5,605,662, 02/25/1997) Heller et al. state, Multiple sample nucleic acid hybridization analysis has been conducted on a variety of filter and solid support formats. It has been developed for multiple analysis of genomic mutations and for the detection of overlapping clones and the construction of genomic maps (see col. 1 lines 42-44 and 54-58)." Heller et al. recognize the advantage of multiplex nucleic acid hybridizations reactions for detection. An ordinary practitioner would have utilized the ETM labels for detection of nucleic acids in an array format in order to analyze multiple sample nucleic acids in a substantially reduced amount of time as compared to analysis of sample nucleic acids separately.

6. Claims 66-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meade et al. (USPN 6,177,250 01/23/2001) in view of Kayyem et al. (USPN 6,096,273, 08/01/2000).

The teachings of Meade et al. are described previously.

Meade et al. do not teach metallocene transition metal complexes. Meade et al. do not teach ferrocine.

With regard to claims 66-69, Kayyem et al. teach the transition metal ferrocine, a metallocene (see col. 36 lines 23).

It would have been prima facie obvious to utilize the method of detection of nucleic acids with ETMs as taught by Meade et al. (USPN 6,177,250 01/23/2001) with ferrocene as transition metal as taught by Kayyem et al. (USPN 6,096,273, 08/01/2000) since Meade et al. state, "Transition metals are those whose atoms have an incomplete d shell of electrons. Suitable transition metals for use in the invention include, but are not limited to, cadmium (Cd), magnesium (Mg), copper (Cu), cobalt (Co), palladium (Pd), zinc (Zn), iron (Fe), ruthenium (Ru), rhodium (Rh), osmium (Os), rhenium (Re), platinium (Pt), scandium (Sc), titanium (Ti), Vanadium (V), chromium (Cr), manganese (Mn), nickel (Ni), Molybdenum (Mo), technetium (Tc), tungsten (W), and iridium (Ir) (see col. 7 lines 41-50). Ferrocine is a transition metal and therefore equivalent to the metals disclosed by Meade et al. Further Kayyem et al. exemplify ferrocine as an ETM in col. 36 line 23. An ordinary practitioner would have been motivated to utilize the method of detection of nucleic acids with ETMs as taught by Meade et al. with ferrocene as transition metal as taught by Kayyem et al. because ferrocine is equivalent to the transition metals disclosed by Medae and Kayyem exemplifies the use of ferrocine as a preferred transition metal for ETMs.

Response to Arguments

7. Applicant's arguments filed May 16, 2005, have been fully considered but they are not persuasive.

Applicant's argue that the references do not anticipate new claims 60-69. For the reasons set forth in the above rejections, new claims 60-69 stand rejected.

Summary

8. No claims allowed.

Correspondence

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather G. Calamita whose telephone number is 571.272.2876 and whose e-mail address is heather.calamita@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner can normally be reached on Monday through Thursday, 7:00 AM to 5:30 PM.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at 571.272.0782.

Papers related to this application may be faxed to Group 1637 via the PTO Fax Center using the fax number 571.273.8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to 571.272.0547.

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hgc

JEFFREY FREDMAN
PRIMARY EXAMINER
6/10/05